DEPARTMENT OF HEALTH & HUMAN SERVICES M996 N

Public Health Service

DB 6/17/97

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

June 13, 1997

WARNING LETTER

Meri C. Russell, President
Mortar & Pestle Pharmacy, Inc.
3701 Beaver Avenue
Des Monies, Iowa 50310

Re.# - KAN-97-017

Dear Ms. Russell:

An inspection of your veterinary drug compounding operation, located at the above address, conducted by an investigator from this office on January 27, through 30, 1997, disclosed significant violations of the Federal Food, Drug and Cosmetic Act (Act).

The FDA's Center of Veterinary Medicine (CVM) will exercise its enforcement discretion in a manner that permits pharmacists, within certain limits, to compound medically necessary animal drugs extemporaneously based on a veterinarian's order. However, your firm's operations include certain activities that FDA has determined go beyond the limits for discretion. These include, but are not limited to:

* The use of bulk substances in circumstances that create a public health concern. Compounded products made from bulk drugs that are used in food animals present a safety concern because of the possibility that unsafe residues could occur.

* Promotion and related activities intended to increase sales of your compounded products. Your firm has promotional materials prepared for various disease conditions which list specific products

to be used in treating these conditions. Most of the products listed are your compounded products. This type of promotional activity serves to establish specific disease treatment uses for your products which are not generally recognized as safe and effective for these uses. It tends to undermine the use of approved products with established safety and effectiveness.

* Veterinarian - Client - Patient Relationship - The prescription order often fails to record critical information necessary to establishing a medical need for a specific patient. Orders frequently fail to indicate the patient name, or other identifying information, the client name and directions for use. The labels bear expiration dates which are a set period of time rather than the veterinarian's treatment period. Compounded drugs for food animals do not bear a withdrawal time established by the veterinarian.

Various veterinary drugs prepared and distributed by your firm are new animal drugs within the meaning of Section 201(v) of the Act. These drugs include, but are not limited tc . These drugs are adulterated under Section 501(a)(5) because they are unsafe within the meaning of Section 512 of the Act. Section 512, in part, deems a new animal drug to be unsafe unless an approved New Animal Drug Application (NADA) is in effect for the specific product in question. None of the drugs you prepare and distribute are the subject of an approval.

Courts have consistently held that the drug approval requirements of the Act apply to drugs that are compounded by pharmacists and practitioners. FDA does not intend to interfere with traditional extemporaneous compounding when driven by the medical needs of a specific animal, as determined by the practitioner, which cannot be met by the use of an approved drug. FDA will exercise its enforcement discretion to permit such compounding. However, we believe that the routine compounding of new animal drugs which are not based on the immediate medical need of a specific animal(s) undermines the mission given to FDA by Congress to assure that animal drugs are safe and effective and

compromises the legislative structure established by Congress to protect the public health. Our enforcement discretion does not extend to compounded drugs which have been specifically promoted for unapproved uses and compete with drugs of known safety and effectiveness.

The above enumeration of deficiencies should not be construed as an all-inclusive list of violations which may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are meet. The Iowa Board of Pharmacy Examiners also found several deviations from their drug compounding controls. Such deviations can cause your veterinary drug products to be adulterated within the meaning of the Good Manufacturing Practices, Section 501(a)(2)(B) of the Act.

Observations include, but are not limited to the following:

1. Failure to list all equipment and utensils, and the container/closure system, relevant to the sterility and stability of the intended use of the drug product.

2. Failure to have written procedures that describes the tests or examinations to be conducted on the product being compounded. Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include ***adequacy of mixing to ensure uniformity and homogeneity ***.

The above is not intended to be an all-inclusive list of violations. As a manufacturer/compounder of veterinary drug products, you are responsible for assuring that your overall operation and your products are in compliance with the law. At the conclusion of the inspection a Form FDA 483, Inspectional Observations, was issued to and discussed with you. This form is a comprehensive listing of the investigator's observations found during the inspection.

We acknowledge your February 7, 1997, response to these observations following our inspection. However, it is not clear to us that these corrections will offset the promotional efforts of your firm in marketing unapproved products. As you were told in a May 3, 1994, letter "we expect to be convinced that a legitimate medical need exists and that alternate approved treatments are not available or will not work under the specific conditions" before compounding is subject to any enforcement discretion. We also stated in that letter that "the use of a compounded product should be a last resort." In our view, sales of these unapproved products are not driven by a well documented medical need but by the marketing and promotional practices of your firm.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within (15) working days, state the reason for the delay and the time within which the corrections will be completed. You may address your reply to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District